United States District Court
Southern District of New York

Jennifer Slanger-Smith -Plaintiff- v. Merck & Co., Inc. -Defendant-	Civil Action No.: 08-3195 COMPLAINT JURY TRIAL DEMANDED

PARTIES - PLAINTIFF

1. Plaintiff, Jennifer Slanger-Smith, is a citizen of the State of MT.

DEFENDANT

2. The Defendant, Merck & Co., Inc., (hereinafter "Merck"), is a corporation organized and doing business in the State of New Jersey, with its principal place of business at One Merck Drive, White House Station, New Jersey 08889.

3. At all times herein mentioned, Defendant did business in the State of Augusta.

4. At all times relevant hereto, Defendant Merck was and continues to be engaged in the business of testing, developing, manufacturing, distributing, licensing, labeling and marketing, either directly or indirectly through third parties or related entities, the pharmaceutical drug, FOSAMAX.

JURISDICTION

5. This Court has original jurisdiction over this action under 28 U.S.C. § 1332, in that the amount in controversy exceeds seventy five thousand dollars ($75,000.00) and Plaintiff is

a citizen of a State which is different from the State where defendant is incorporated and has its principal place of business.

FACTS

6. FOSAMAX ("alendronate sodium") is a bisphosphonate used to treat osteoporosis (thin bones). It is a medicine prescribed and sold for the prevention of osteoporosis in postmenopausal women, for the treatment of osteoporosis in postmenopausal women, for increasing bone mass in men with osteoporosis, for men and women with low bone mass who take glucocorticoids, and for the treatment of Paget's disease of bone in both men and women.

7. United States Food and Drug Administration approved the use of FOSAMAX.

8. Upon information and belief, on or before 2002, a physician notified Merck that 90 or more patients taking FOSAMAX had lost portions of their jaws.

9. Upon information and belief, oral surgeons reported the same danger to Merck. Nevertheless. Merck did not warn doctors or its consumers of this danger until October of 2004.

10. Plaintiff, as a person taking FOSAMAX was at risk for developing osteonecrosis of the jaw (ONJ) because these bisphosphonates irreversibly inhibit osteoclasts. In addition, because the jaws have a greater blood supply than other bones and a faster bone turnover rate related to their daily activity and the presence of teeth, these bisphosphonates are highly concentrated in the jaw. This combined with invasive dental diseases and/or treatments causes the condition to typically manifest itself in the jaw.

11. Plaintiff, as a person taking FOSAMAX was at increased risk of developing osteonecrosis of the jaw even after the bisphosphonate therapy is stopped because these drugs irreversibly inhibit osteoclasts. They concentrate themselves in the jawbone and when the patient suffers an invasive dental disease or dental treatment the jaw will not heal and may progress to ONJ.

12. There were no warnings from Merck about osteonecrosis of the jaw until July 2005. The warnings remain inadequate to date with regard to ONJ.

13. Upon information and belief, to date no adequate warning about the potential danger of dental intervention and the development of osteonecrosis of the jaw (ONJ) has been provided to the dental community.

14. Plaintiff purchased and ingested FOSAMAX from 2006 to May 2006.

15. Upon information and belief, as a result of plaintiff's FOSAMAX ingestion she suffered osteonecrosis of the jaw.

COUNT I

PRODUCTS LIABILITY – DEFECTIVE DESIGN

16. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

17. Defendant is the researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of FOSAMAX, which is defective and unreasonably dangerous to consumers.

18. FOSAMAX is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits

associates with its design and formulation. FOSAMAX is defective in design or formulation in that it lacks efficacy and/or it is more dangerous than ordinary consumers can reasonably foresee.

19. The defective condition of FOSAMAX renders it unreasonably dangerous, and FOSAMAX was in this defective condition at the time it left the hands of the Defendant. FOSAMAX was expected to and did reach consumers, including Plaintiff, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

20. Plaintiff was unaware of the significant hazards and defects in FOSAMAX. FOSAMAX was unreasonably dangerous in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiff was taking FOSAMAX, the medication was being utilized in a manner that was intended by Defendant. At the time Plaintiff received and consumed FOSAMAX, it was represented to be safe and free from latent defects.

21. Defendant Merck is strictly liable to Plaintiff for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendant because of the design defects.

22. Defendant Merck knew or should have known of the danger associated with the use of FOSAMAX, as well as the defective nature of FOSAMAX but has continued to design, manufacture, sell, distribute, market, promote and/or supply FOSAMAX so as to

maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by FOSAMAX.

23. As a direct and proximate cause of the design defect and Defendant's misconduct as set forth herein, Plaintiff has suffered and continues to suffer serious and permanent physical and emotional injuries, has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

WHEREFORE, Plaintiff demands judgment against Defendant Merck for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II

PRODUCTS LIABILITY – DUTY TO WARN

24. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

25. Defendant Merck researched, developed, designed, tested, manufactured, inspected, distributed, marketed, promoted, sold and otherwise released into the stream of commerce the pharmaceutical, FOSAMAX, and in the course of same, directly advertised or marketed the product to FDA, consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of FOSAMAX.

26. FOSAMAX was under the exclusive control of the Defendant as aforesaid, and was unaccompanied by appropriate warnings regarding all possible adverse side effects and

complications associated with the use of FOSAMAX, dangerous drug-drug interactions and the comparative severity, duration and the extent of the risk of injury with such use.

27. Defendant Merck has failed to timely and reasonably warn of material facts regarding the safety and efficacy of FOSAMAX so that no medical care provider would have prescribed, or no consumer would have used FOSAMAX had those facts been made known to such providers and consumers.

28. Defendant Merck has failed to timely and reasonably warn the dental community of material facts regarding the efficacy of undergoing dental interventions on persons taking FOSAMAX because of their risk for developing ONJ.

29. Defendant Merck's July 2005 warnings are inadequate to reasonably warn of the material facts regarding the safety and efficacy of FOSAMAX so that no medical care provider would have prescribed, or no consumer would have used FOSAMAX if those facts had been made known to such providers and consumers.

30. Defendant Merck's July 2005 warnings are inadequate to reasonably warn the dental community of the material facts regarding the undertaking of dental procedures on persons/consumers using FOSAMAX.

31. Defendant Merck failed to perform or otherwise facilitate adequate testing in that such testing would have shown that FOSAMAX posed serious and potentially life-threatening side effects and complications with respect to which full and proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to medical care providers, the FDA, and the public including the Plaintiff.

32. FOSAMAX, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the

stream of commerce by Defendant, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendant knew or should have known of the risk of serious and potentially life-threatening side effects and complications from the use of FOSAMAX, Defendant failed to provide adequate warnings to medical care providers, the FDA, the dental community and the consuming public, including Plaintiff, and continued to promote FOSAMAX aggressively.

33. As a direct and proximate result of the conduct of Defendant Merck as aforesaid, Plaintiff has suffered and continues to suffer from serious and permanent physical and emotional injuries, has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff demands judgment against Defendant Merck for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III

PRODUCTS LIABILITY – FAILURE TO WARN

34. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

35. Plaintiff repeats and incorporates by referenced all other paragraphs of the Complaint as if fully set forth herein.

36. Defendant Merck is the researcher, developer, designer, tester, manufacturer, inspector, labeler, distributor, marketer, promoter, seller and/or otherwise released FOSAMAX into the stream of commerce.

37. Defendant Merck knew or should have known that the use of FOSAMAX causes serious and life threatening injuries but failed to warn physicians and the public, including Plaintiff, of same.

38. Defendant Merck knew or should have known that undertaking dental intervention on persons using FOSAMAX causes serious and life threatening injuries but failed to warn the dental community of same.

39. In violation of the Act, Defendant Merck made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts from Plaintiff in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, among other ways, regarding the safety of FOSAMAX. Moreover, Defendant downplayed and/or understated, and/or failed to reveal the serious nature of the risks associated with FOSAMAX in order to increase the sales of FOSAMAX.

40. Defendant's statements and omissions were undertaken with the intent that the FDA, physicians, the dental community and consumers, including the Plaintiff, would rely on the Defendant's statements and/or omissions.

41. Defendants knew of the growing public acceptance of the misinformation and misrepresentation regarding the safety and efficacy of FOSAMAX but remained silent because Merck's appetite for significant future profits far outweighed its concern for the health and safety of the Plaintiff.

42. Plaintiff's physician prescribed and/or otherwise provided Plaintiff with FOSAMAX and Plaintiff consumed FOSAMAX, primarily for personal and family reasons and suffered

ascertainable losses of money as a result of the Defendant's use or employment of the methods, acts, or practices alleged herein.

43. The aforesaid promotion and release of FOSAMAX into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or knowing concealment, suppression or omission in connection with the sale or advertisement of such merchandise or services by Defendant.

44. Defendant Merck concealed, omitted, or minimized the side effects of FOSAMAX or provided misinformation about adverse reactions, risks, and potential harm from FOSAMAX and succeeded in persuading consumers to purchase and ingest FOSAMAX despite the lack of safety and the risk of adverse medical reactions.

45. Defendant Merck's practice of promoting and marketing FOSAMAX created and reinforced a false impression as to the safety of FOSAMAX, thereby placing consumers at risk of serious and potential lethal effects.

46. FOSAMAX lacked appropriate warnings, and the packaging and labels used by Defendant were misleading, inaccurate, incomplete, and/or untimely.

47. Defendant Merck violated its post-manufacture duty to warn which arose when Merck knew, or with reasonable care should have known, that FOSAMAX was injurious.

48. At the time when consumers purchased and ingested FOSAMAX, Defendant Merck intended that others would rely upon concealment, suppression or omission of the risks of ingesting FOSAMAX.

49. Defendant's actions in connection with manufacturing, distributing, and marketing of FOSAMAX as set forth herein evidence a lack of good faith, honesty in fact and observance of fair dealing so as to constitute unconscionable commercial practices.

50. Defendant Merck acted willfully, knowingly, intentionally, unconscionable and with reckless indifference when committing these acts of consumer fraud.

51. As a proximate results of consumer fraud set forth above, Plaintiff has purchased an unsafe product and incurred monetary expense and the risk to themselves and members of their household that they would consume FOSAMAX and thereby suffer an increased risk of harm as previously set forth herein.

WHEREFORE, Plaintiff demands judgment against Defendant Merck for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV

BREACH OF EXPRESS WARRANTY

52. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

53. Defendant Merck placed FOSAMAX into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the dental community, the FDA and consumers, including the Plaintiff of the risks associated with the use of FOSAMAX.

54. Defendant Merck had a duty to exercise reasonable care in the research, development, design, testing, manufacture, inspection, labeling, distribution, marketing, promotion, sale and release of FOSAMAX, including duty to:

a. Ensure that the product did not cause the user unreasonably dangerous side effects;

b. Warn of dangerous and potentially fatal side effects; and

c. Disclose adverse material facts when making representations to physicians, the dental community, the FDA and the public at large, including Plaintiff.

55. When the plaintiff's physician prescribed FOSAMAX and Plaintiff made the decision to use FOSAMAX, both Plaintiff and their physicians reasonably relied upon the Defendant and its agents to disclose known defects, risks, dangers and side effects of FOSAMAX.

56. Plaintiff's physicians, the dental community, the FDA and/or Plaintiff had no knowledge of the falsity or incompleteness of the Defendant's statements and representations concerning FOSAMAX when Plaintiff's physician prescribed and/or otherwise provided FOSAMAX and Plaintiff purchased and used FOSAMAX as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by the Defendant. Plaintiff justifiably and detrimentally relied on the warranties and representations of Defendant in the purchase and use of FOSAMAX.

57. Defendant Merck was under a duty to disclose the defective and unsafe nature of FOSAMAX to physicians, the dental community, the FDA, consumers and users, such as Plaintiff. Defendant had sole access to material facts concerning the defects, and Defendant knew that physicians, the dental community, the FDA and users, such as Plaintiff, could not have reasonably discovered such defects.

58. By the conduct alleged, Defendant Merck, its agents and employees expressly warranted to Plaintiff and Plaintiff's physician(s) that the products were merchantable and fit for purpose intended.

59. This warranty was breached because FOSAMAX was not safe and effective as a medication for the prevention and treatment of osteoporosis, as Defendant had represented, and Plaintiff was injured.

60. As a direct result of Defendant's conduct as aforesaid, Plaintiff has suffered and continues to suffer serious and permanent physical and emotional injuries, has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff demands judgment against Defendant Merck for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V

PUNITIVE DAMAGES

61. Plaintiff repeats and incorporates by reference all other paragraphs of the Complaint as if fully set forth herein.

62. The Plaintiff is entitled to punitive damages because the Defendant's failure to warn was reckless and without regard for the public's safety and welfare. The Defendant misled both the medical community, the dental community and public at large, including the Plaintiff herein by making false representations about the safety of FOSAMAX. Defendant downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of FOSAMAX despite available information demonstrating that FOSAMAX was likely to cause serious and even fatal side effects to users.

63. The Defendant's conduct was reckless and without regard for the public's safety and welfare in having failed to warn consumers and physicians of the material facts regarding the safety and efficacy of Fosamax for a period of approximately one-year subsequent to the FDA 's notification to so warn.

64. The Defendant's conduct was reckless and without regard for the public's safety and welfare in having failed to notify pre-2005 consumers of Fosamax about the material facts regarding the safety and efficacy of Fosamax, including but not limited to the increased risk of developing osteonecrosis of the jaw (ONJ) and the association between undergoing dental procedures and the development of said condition.

65. Defendant was or should have been in possession of evidence demonstrating that FOSAMAX caused serious side effects. Nevertheless, Defendant continued to market FOSAMAX by providing false and misleading information with regard to safety and efficacy.

66. Defendant failed to provide warnings that would have dissuaded physicians from prescribing FOSAMAX and consumers from purchasing and consuming FOSAMAX, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing FOSAMAX.

67. Defendant failed to provide a warning that would have dissuaded members of the dental community from performing dental interventions on consumers using FOSAMAX, thus depriving members of the dental community and consumers from weighing the risks of undergoing such dental procedures.

WHEREFORE, Plaintiff demands judgment against Defendant Merck for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

RELIEF REQUESTED

WHEREFORE, Plaintiff demands judgment against Defendant Merck as follows:

A. Awarding Plaintiff compensatory damages against Defendant in an amount sufficient to fairly and completely compensate Plaintiff for all damages;

B. Awarding Plaintiff treble damages against Defendant so to fairly and completely compensate Plaintiff for all damages, and to deter similar wrongful conduct in the future;

C. Awarding Plaintiff punitive damages against Defendant in an amount sufficient to punish Defendant for its wrongful conduct and to deter similar wrongful conduct in the future;

D. Awarding Plaintiff costs and disbursements, costs of investigations, attorneys' fees and all such other relief available;

E. Awarding that the costs of this action be taxed to the Defendant;

F. Awarding such other and further relief as the Court may deem just and proper.

Plaintiff's Counsel
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Dated: March 20, 2008

DEMAND FOR JURY TRIAL

Plaintiff respectfully requests a trial by jury on all triable issues pursuant to Rule 38 of the Federal Rules of Civil Procedure.

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Dated: March 20,2008